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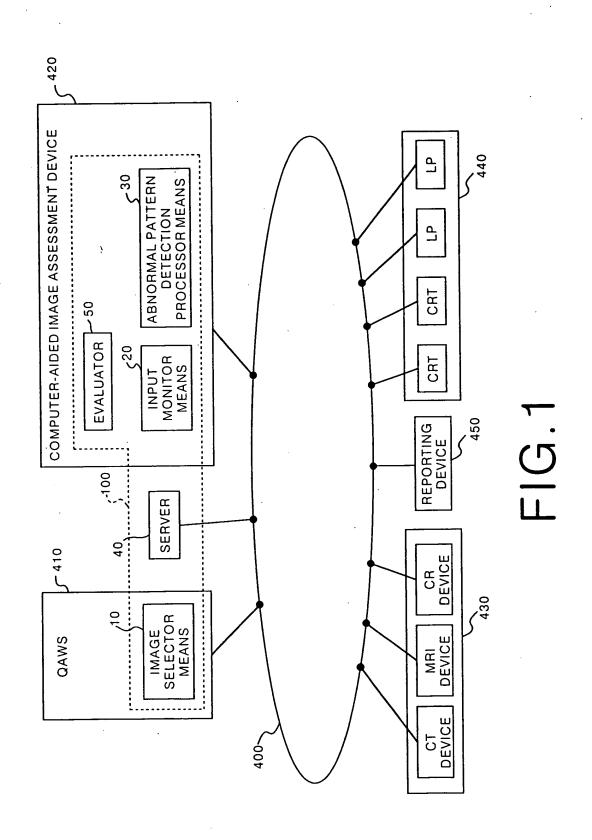


FIG.2A

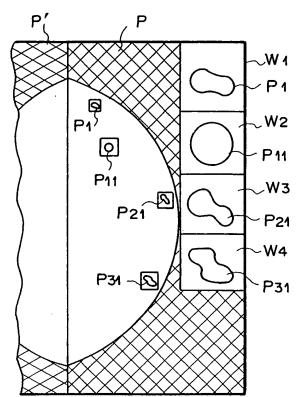
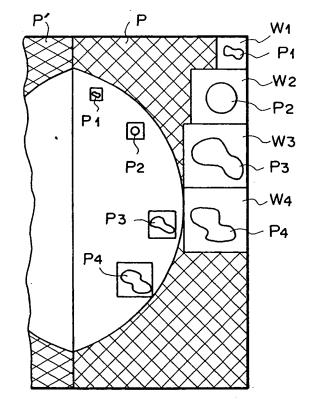


FIG.2B



[PATIENT INFORMATION]

1) PATIENT'S NAME, AND PATIENT'S ID

② PATIENT'S DATE OF BIRTH (YEARS OLD)

3 NAME OF CLINICIAN IN CHARGE

(A) NAME OF RADIOLOGIST (REPORTER)

[BREAST COMPOSITON]

1. BRIEF DESCRIPTION OF OVERVIEW OF ENTIRE MAMMOGRAM

1) FAT (GENERALLY FAT/ADIPOSE)

② FIBROGIANDULAR (DISTRIBUTED AT SPARSE DENSITY)

(3) HETEROGENEOUSLY (HETEROGENEOUSLY THICKSET)

2. DETECTION RESULT

a-MASS

a-1 SIZE

a-2 GEOMETRY/DENSITY

a-3 EXISTENCE OF CALCIFICATION

a-4 ASSOCIATED FINDINGS

a-5 LOCATION

b-CALCIFICATIONS

b-1 GEOMETRY

b-2 DENSITY

b-3 ASSOCIATED FINDINGS

b-4 LOCATION

* WHEN A PAST IMAGE IS AVAILABLE, RECORD WHAT CHANGE OCCURS.

* WHEN THE NIPPLE IS REGARDED AS THE CENTER OF A CLOCK, INDICATE

THE DIRECTION WHAT O'CLOCK THE LOATION IS IN.

3. DESCRIPTION OF GENERAL IMPRESSION (SUMMARY)

[ASSESSMENT CATEGORIES]

IN ACCORDANCE WITH THE FOLLOWING CATEGORIES (WHICH ARE CALLED BI-RADS TM CATEGORIES), THE RADIOLOGIST SHALL INDICATE THE RESULT OF PATTERN READING.

c-ARCHITECTUAL DISTORTION

c-3 LOCATION

c-3 LOCATION

d-SPECIAL CASES

C-2 ASSOCIATED FINDINGS

C-2 ASSOCIATED FINDINGS

C-1 EXISTENCE OF CALCIFICATION

C-1 EXISTENCE OF CALCIFICATION

CATEGORY 0: NEED ADDITIONAL IMAGE EVALUATION.

CATEGORY 1: NEGATIVE--THERE IS NOTHING TO BE COMMENTED.

CATEGORY 2: BENIGN FINDING.

CATEGORY 3: PROBABLY BENIGN FINDING--NEED SHORT TERM FOLLOW-UP.

CATEGORY 4: THERE IS HIGH POSSIBILITY OF MALIGNANCY. SUSPICIOUS

ABNORMALITY--NEED FOR BIOPSY TO BE EXAMINED.

CATEGORY 5: MALIGNANT, HIGH SUGGESTIVE OF MALIGNANCY--AN APPROPRIATE

MEASURE TO BE TAKEN.

Hanako Yamada

DOB: 11 / 5 / 43

Referring Physician: Ichiroh Fuji

BILATERAL SCREENING MAMMOGRAMS

March 1, 1998

Clinical History: Screen.

Compared with the prior study of 2 / 1 / 97, there are again scattered fibroglandular densities bilaterally.

IMPRESSION:

No change from prior examination. No mammographic evidence of malignancy. Yearly mammograms are recommended.

BI-RADS TM CATEGORY 1:

Negative.

Taroh Tokyo Radiologist

DETACHABLE REFERENCE FOR BIOPSY RESULTS

BIOPSY RESULTS

	POSITIVE (BIOPSY DEMONSTRATED MALIGNANCY)	NEGATIVE (BIOPSY IS BENIGN OR NO CANCER DISCOVERED WITHIN ONE YEAR)
MAMMOGRAM POSITIVE (BI-RADS TM CATEGORIES 0, 4, 5)	TP	FP
MAMMOGRAM NEGATIVE (BI-RADS TM CATEGORIES 1, 2, 3)	Z.	Z. F

SCREENING TEST FOR CANCER

SENSITIVITY=TP/(TP+FN) SPECIFICITY=TN/(TN+FP) PPV=TP/(TP+FP)

SAMPLED DATA COLLECTION

BASIC CLINCIAL RELEVANT AUDIT, SCREENING CASES ONLY FORM A

DATA ITEM

RESULTS

		l l
	TOTAL SCREENING CASES	•
	TOTAL SCREENING CASES, ASSESSMENT BI-RADS TM CATEGORY 0, (NEEDS ADDITIONAL IMAGING EVALUATION) AND SCREENING CASES GIVEN ASSESSMENT BI-RADS TM CATEGORY 4 OR 5, WITHOUT FURTHER EVALUATION	
#3	TOTAL SCREENING CASES, <u>FINAL</u> ASSESSMENT BI- RADS TM CATEGORY 4	
#4	TOTAL SCREENING CASES, <u>FINAL</u> ASSESSMENT BI- RADS TM CATEGORY 5	
#5	TOTAL CASES FROM FINAL ASSESSMENT BI-RADS TM CATEGORIES 4 AND 5 THAT UNDERWENT CORE BIOPSY/FNA	
	#5A NUMBER OF THESE THAT WERE MALIGNANT	
	#5B NUMBER OF THESE THAT WERE BENIGN	
#6	TOTAL CASES FROM FINAL ASSESSMENT BI-RADS TM CATEGORIES 4 AND 5 THAT UNDERWENT SURGICAL BIOPSY	
 	#6A NUMBER OF THESE THAT WERE MALIGNANT	
	#6B NUMBER OF THESE THAT WERE BENIGN	
#7	TOTAL CASES FROM FINAL ASSESSMENT BI-RADS TM CATEGORIES 4 AND 5 THAT WERE LOST TO FOLLOW-UP, REFUSED BIOPSY, OR SURGEON ELECTED TO FOLLOW RATHER THAN BIOPSY	
#8	TOTAL CANCERS FOUND THAT WERE DUCTAL CARCINOMA IN SITU	
#9	TOTAL CANCERS FOUND THAT WERE INVASIVE DUCTAL CARCINOMA OR INVASIVE LOBULAR CARCINOMA	
#1	TOTAL CANCERS FOUND THAT WERE INVASIVE DUCTAL CARCINOMA OR INVASIVE LOBULAR CARCINOMA FOR WHICH AXILLARY SAMPLING WAS PERFORMED	
#1	1 TOTAL NUMBER OF INVASIVE CANCERS THAT WERE ≤ 1cm IN SIZE	·
#1	2 TOTAL NUMBER OF INVASIVE CANCERS THAT SHOWED POSITIVE AXILLARY LYMPH NODES AT SURGERY	

NOTE: BI-RADS TM CATEGORY 3 CASES ARE NOT LISTED HERE BECAUSE THEY ARE CONSIDERED NEGATIVE.

SAMPLE CALCULATION (DERIVED DATA)

BASIC CLINCIAL RELEVANT AUDIT, SCREENING CASES ONLY

FORM B

PARAMETER TO BE CALCULATED

EQUATION*

RESULT

PAKAMELEK 10 BE CALCOLATED		
NUMBER OF TRUE POSITIVE (TP)	5A+#6A	
NUMBER OF FALSE POSITIVES (FP) THREE DEFINITIONS:		
FP,	#2-TP	
FP2	#28+#68+#7	
FP ₃	#5B+#6B	
POSITIVE PREDICTIVE VALUE THREE DEFINITIONS:		
PPV ₁ (HOW OFTEN ABNORMAL SCREENS ARE CANCER)	[TP]/#2	
PPV ₂ (HOW OFTEN BIOPSIES RECOMMENDED ARE CANCER)	[TP]/[TP+FP2]	
PPV ₃ OR BPR (HOW OFTEN BIOPSIES DONE ARE CANCER)	[TP]/[TP+FP3]	
CANCER DETECTION RATE	·([TP]/[#1])×1000	
PERCENT MINIMAL CANCERS (INVASIVE CANCERS < 1cm, OR DUCTAL CARCINOMA IN SITU) FOUND	([#8+#11]/[TP])×100	
PERCENT AXILLARY NODE-POSITIVE INVASIVE CANCER FOUND	(#12]/[#0])×100	
% RECALL (i.e. RECALL RATE)	([#2]/[#1])×100	

^{*} NUMBER REFER TO DATA ITEMS ON FORM A

PRACTICE DATA SET FOR FORMS A AND B

PLEASE USE THE FOLLOWING HYPOTHETICAL DATA SET FOR FORM A AS A PRACTICE EXERCISE FOR PERFORMING THE REQUISITE CALCULATIONS OF FORM B FOR THE BASIC AUDIT.

1.	5000
2.	450
3.	50
4.	40
5.	43
5A.	15
5B.	28
6.	42
6A.	15
6B.	27
7.	5
8.	6
9.	24
10.	23
11.	9
12.	4

ANSWERS TO CATEGORIES ON FORM B:

```
TP=30
FP_1=420
FP_2=60
FP_3=55
PPV_1=.07(7\%)
PPV_2=.33(33\%)
PPV_3=.35(35\%)
CANCER DETECTION RATE=6/1000
% MINIMAL CANCERS=50%
%NODE POSITIVE INVASIVE CANCERS=17%
RECALL RATE=9%
```

FIG.9

